NDA 17-090/S-067

Mallinckrodt Inc.
Attention: Russell D. Reed
Regulatory Affairs
675 McDonnell Boulevard
P.O. Box 5840
Saint Louis, MO 63134-0840

Dear Mr. Reed:

We acknowledge receipt of your supplemental new drug application dated November 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tofranil-PM (imipramine pamoate) 75 mg, 100 mg, 125 mg, and 150 mg Capsules.

Supplemental application S-067, submitted under "Changes Being Effected", provides for revisions to the **HOW SUPPLIED** section to reflect the changes of name and address of distributor of the drug.

We have completed the review of this supplemental application, S-067, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted November 29, 2001/Label Code 750-01440), which incorporates all of the revisions listed above. Accordingly, this supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
1/3/02 08:01:46 AM